Initial Licence Inspection Report

Date of Inspection: 16 October 2012
Length of inspection: 7 hours
Inspectors: Vicki Lamb
Janet Kirkland
Parvez Qureshi
Jenny Clifford

Inspection details:
The report covers the pre-inspection analysis, the visit and information received with the new licence application.

Date of Licence Committee: 29 November 2012

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres have in place processes and procedures to ensure that they will comply with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice (CoP) to ensure that centres will provide a quality service for patients. The report summarises the findings of the inspection. It is primarily written for the Authority's Licence Committee which makes the decision about the centre's licence application.

Centre details - proposed

Centre Name	City Fertility
Centre Number	0324
Centre Address	16 St John Street, London, EC1M 4NT
Person Responsible	Jane Holman
Licence Holder	Andrew Berkley
Proposed date of licence issue	1 December 2012

Contents

Report to Licence Committee

Brief description of the centre:
An initial enquiry was received by the HFEA from Andrew Berkley (the proposed Licence Holder (LH)) on 1 February 2012, regarding licensing requirements for a treatment and storage centre. City Fertility has been incorporated as a private limited company in the United Kingdom.

The centre plans to provide treatment to privately funded patients. The proposed Person Resposible (PR) has stated that the centre will have the designed capacity to perform 1000 in vitro fertilisation (IVF) / intracytoplasmic sperm injection (ICSI) cycles per year and the PR hopes, in the first year of activity, to provide 200 treatment cycles.

Projected activities of the Centre:

Type of treatment	Number of treatment cycles premises designed to accommodate
Intra Uterine Insemination (IUI)/Donor Insemination (DI)	500
IVF/ICSI/Frozen Embryo Transfer (FET)	1000
Preimplantation Genetic Screening (PGS)/Preimplantation Genetic Diagnosis (PGD)	N/A

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	N/A

Summary for licensing decision:

In considering overall compliance, the inspection team considers that there is sufficient information drawn from documentation submitted by the centre prior to and after the inspection and from observations and interviews conducted during the inspection visit, to conclude that:

- The proposed PR satisfies the requirements of section 16 of the HF&E Act 1990 (as amended) necessary for a licence to be granted since:
    1. The proposed PR holds academic qualifications in the field of nursing and is registered with the Nursing and Midwifery Council (NMC); registration number: 89J1425E. The proposed PR also has more than two years' practical experience which is directly relevant to the activities to be authorised by the licence.
    2. The proposed PR has satisfactorily completed the PR entry programme (certificate number: T/1218/8).
    3. Two referees, provided by the proposed PR, have attested to the suitability of the character of the applicant for the post of PR.

- The proposed PR is suitable and will discharge her duty under section 17 of the HF&E Act 1990 (as amended).

- The initial treatment and storage licence application details the appointment of a LH. The proposed LH's CV has been submitted.

- The premises and equipment are suitable with the exceptions described below:

    At inspection, the premises appeared appropriate for the proposed licensable activities and should provide a safe, clean and private environment for patients, their gametes and embryos and centre staff. The premises have been handed over by the contractors to the centre and building regulation certification was made available on the day of the inspection.

    At the time of the inspection, most clinical and laboratory equipment had been purchased. This equipment has been validated.

- The proposed practices and processes are anticipated to be suitable:

    The centre has documented standard operating procedures (SOPs) for the proposed licensed activities and well established processes will be used

    All staff provided evidence that they are suitably experienced to carry out their designated jobs and the PR described appropriate plans to ensure that staff competence to perform their designated roles will be effectively monitored and reviewed.

    The centre has documented quality indicator (QI) monitoring and audit programmes which will allow the PR to identify whether processes are being effectively implemented.

- The proposed PR has submitted documentation to satisfy the requirements of General Direction 0008 (Information to be submitted to the HFEA as part of the licensing process).

- The centre has submitted an application fee to the HFEA in accordance with requirements

The Licence Committee is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one area of critical non-compliance, two areas of major non-compliance and one 'other' area of non-compliance or poor practice.

Since the inspection visit the PR has provided evidence that the following recommendation has been fully implemented:

Major areas of non-compliance:

- The PR should ensure the air quality in the processing areas is assessed and meets the requirements of Standard Licence Condition T20 before treatment is offered.

The PR has given a commitment to fully implement the following recommendations:

Critical area of non-compliance:

- **The PR should ensure that all required equipment is in place and validated prior to treatment being offered.**

Major areas of non-compliance:

- The PR should inform the inspector when the lead embryologist receives confirmation that her Health and Care Professions Council (HCPC) registration application has been accepted.

'Other' areas of practice that require improvement:

- The PR should inform the inspector whether a more suitable counselling room has been found, or how she considers the consultation room to be suitable for counselling.

Recommendation to the Licence Committee:

The inspection team considers that, overall, there is sufficient information available to recommend:

1. Granting a treatment and storage licence for a period of two years without additional conditions, subject to the proposed PR providing evidence of compliance with the non-compliances detailed in the report.

2. Appointment of the proposed PR.

3. Appointment of the proposed LH.

Details of Inspection findings

1. Protection of patients and children born following treatment

Focus
The purpose of the inspection was to assess whether the centre:

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre and of any other child who may be affected by that birth
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned.

▶ **Witnessing and assuring patient and donor identification** (Guidance Note 18)
What the centre does well. The centre has a SOP for witnessing to ensure that no mismatches of gametes or embryos or identification errors occur (SLC T71). This SOP was audited during the inspection and appeared to be compliant with the requirements of CoP guidance note 18.4. The template for recording witnessing also appears to be fit for purpose. All containers for gametes and embryos, including aspirate tubes at egg collection, will be appropriately labelled (SLC T101).
What the centre could do better. Nothing noted.

▶ **Patient selection criteria and laboratory tests** • Procuring, processing and transporting gametes and embryos (Guidance Note 15) • Counselling (Guidance Note 3)
What the centre does well. **Procuring, processing and transporting gametes and embryos** Prior to the processing of patient gametes or embryos intended for use in treatment or storage the centre will screen patients as required by SLC T50. These tests will be

performed by a Clinical Pathology Accreditation (CPA) accredited laboratory (SLC T51).

The centre was able to demonstrate accreditation to a standard equivalent to CPA for diagnostic semen analysis (SLC T21).

If sperm is produced off-site there is a declaration form that will be completed. This will be retained in the patient's notes (SLC T68).

Counselling
There are appropriate counselling SOPs in place (SLC T33b).

Counselling will be offered to patients as required by schedule 3 and schedule 3ZA of the HF&E Act 1990 (as amended). Implications counselling is mandatory for egg and sperm donors and recipients and the cost of this is included in the treatment costs.

The counsellor can offer appointments at the centre or at her home. She can offer day and evening appointments. Two free supportive counselling sessions will be offered with each treatment cycle.

If required, the counsellor can refer patients to specialist genetic counsellors or oncology counsellors (CoP Guidance Note 3.10).

QIs have been established and audits are planned (SLC T35 and T36).

The counsellor has facilities to keep her notes secure and separate from the main medical notes (CoP Guidance Note 3.12).

What the centre could do better.

Nothing noted.

Donor recruitment, assessment and screening (Guidance Note 11)
Payments for donors (Guidance Note 13)
Donor assisted conception (Guidance Note 20)

What the centre does well.

Donor recruitment, assessment and screening
There is an SOP for the recruitment of donors (SLC T33b). The centre staff are aware of the screening requirements for donors and donors will be screened as required by SLC T52. These tests will be performed by a CPA accredited laboratory (SLC T53).

Payments for donors
Centre staff are aware of the limitations for compensation for donors (General Directions 0001).

Donor assisted conception
Patients will be informed of the importance of informing any child at an early age that the child results from the gametes of a person who is not their parent and patients will be provided with information on how to tell the child (SLC T63).

What the centre could do better.

Nothing noted.

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)
- Intracytoplasmic sperm injection (ICSI) (Guidance Note 21)

What the centre does well.

Quality management system (QMS)
There is a comprehensive quality management system in place (SLC T32). This consists of a quality manual, SOPs and associated documents (SLC T33).

There are SOPs for all activities that the centre wishes to include on the licence and for those activities carried out in the course of providing treatment services that do not require a licence (SLC T33b). These SOPs detail the specifications for critical materials and reagents (SLC T31).

QIs have been established (SLC T35) and there is an audit programme in place (SLC T36).

An annual review of the QMS will be conducted (HF&E Act schedule 3A (10)).

Traceability
There is an SOP to ensure traceability of gametes, embryos, consumables and equipment (SLC T22, T99 and T102) and to ensure the accurate identification of patients, gametes and embryos (SLC T100). Containers will be appropriately labelled (SLC T101).

Validation
The centre staff will be using established protocols for critical procurement and processing procedures. Validation reports are in place and ongoing validation will be performed (SLC T72).

Equipment and materials
Activities will be carried out using equipment designed for the purpose (SLC T23). Service agreements are in place for equipment that is already on site (SLC T26). Equipment will be regularly inspected and maintained and critical equipment that is already on site has been validated (SLC T24). The record sheets for recording servicing and maintenance were provided during the inspection. There are documented procedures for the operation of all critical equipment and these outline what to do if the equipment malfunctions or fails (SLC T27). Equipment is fitted with alarms where appropriate and equipment with a critical measuring function will be appropriately calibrated (SLC T24).

Sterile equipment and devices will be used throughout the centre (SLC T28). No reuseable instruments will be used (SLC T29).

Wherever possible, CE marked consumables will be used and evidence of this was provided during the inspection (SLC T30).

Premises
The inspection team considered the premises to be suitable (SLC T17). The main entrance has secure access arrangements and rooms where records, gametes or embryos may be kept have secure access.

There is an uninterrupted power supply that will provide four hours of battery power to critical equipment in case of unexpected power failure. There is a contingency arrangement in place with another licensed centre in case of unexpected events which prevent the centre from operating.

There are cleaning records held for the premises (SLC T26).

Adverse incidents
Centre staff are aware of the requirements for reporting and investigating adverse incidents and an SOP for this is in place (SLC T118 and T119).

Arrangements are in place for taking patients from the upper floors of the premises to the ground floor to access an ambulance in an emergency.

Third Party agreements
Third party agreements are in place with suppliers (SLC T111) and these comply with SLC T113, T114 and T116.

A list of all third party agreements is maintained (SLC T115).

Intracytoplasmic sperm injection (ICSI)
Laboratory staff who perform ICSI will be appropriately trained and have their competence assessed (SLC T15). Staff are aware of the contents of CoP Guidance Note 21.

What the centre could do better.

At the time of the inspection not all the necessary theatre and laboratory equipment was present at the centre, but the PR gave assurances that this would be in place before

treatments were offered. (SLC T17).

Centre staff proposed that counselling would take place in one of the consultation rooms. The inspection team were concerned that this may not offer appropriately quiet and comfortable surroundings (CoP Guidance Note 3.11).

The air quality in the processing areas has not yet been assessed but the PR is aware of the requirement to do so prior to offering treatments (SLC T20).

Multiple Births (Guidance Note 7)

What the centre does well

The centre has a multiple births minimisation strategy in place which is compliant with General Directions 0003. Audits of the effectiveness of this strategy are planned.

Centre staff are aware of the requirements of General Directions 0003.

What the centre could better

Nothing noted.

Staff engaged in licensed activity

- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

What the centre does well

Person Responsible
The PR has academic qualifications in the field of nursing and has more than two years of practical experience which is directly relevant to the activities to be authorised by the licence as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii).

The proposed PR has completed the PR Entry Programme (PREP) and achieved the pass mark.

Staff
The lead embryologist is being registered by HCPC through the international route (SLC T14). It is anticipated that confirmation of whether her application has been accepted will be known by the end of December 2012. She was available for interview at the time of the inspection and information obtained during the interview, along with the training and experience described in the CV appeared to demonstrate her suitability for the role of lead embryologist at the centre.

The accredited consultant is registered with the General Medicine Council (GMC) (SLC T14). He was available for interview at the time of the inspection and information obtained during the interview, along with the training and experience described in the CV appeared to demonstrate his suitability for the role of accredited consultant at the centre (SLC T16).

The lead counsellor is accredited with the British Infertility Counselling Association (BICA) (SLC T14). The counsellor was available for interview at the time of the inspection and information obtained during the interview, along with the training and experience described in the CV appeared to demonstrate her suitability for the role of counsellor at the centre.

The lead nurse, who is also the proposed PR, is registered with the NMC (SLC T14). She was available for interview at the time of the inspection and information obtained during the interview, along with the training and experience described in the CV appeared to demonstrate her suitability for the role of lead nurse at the centre.

There are documented induction and training procedures for all staff and these were provided to the inspection team (SLC T15). Arrangements for competence assessments are in place and processes have been established for all staff to participate in continuing professional development.

What the centre could do better.

The lead embryologist is not yet registered with the HCPC but has applied to be registered through the international route (SLC T14).

Welfare of the Child (Guidance Note 8)

What the centre does well.

There is an SOP for conducting welfare of the child assessments. Account will be taken of the welfare of any child who may be born as a result of treatment and of any other child who may be affected by the birth, before treatment is provided (SLC T56). If asked for an opinion, the counsellor will write a factual report with the consent of the patient.

What the centre could do better.

Nothing noted.

2. Patient Experience

Focus

The purpose of the inspection visit was to assess whether the centre:

- treats prospective and current patients and donors fairly and ensures that all licensed activities are conducted in a non-discriminatory way
- has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- ensures that patients and donors have provided all relevant consents before carrying out any licensed activity

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Complaints (Guidance Note 28)
- Provision of costed treatment plans (Guidance Note 4)

What the centre does well

Treating patients fairly
The centre's policies and procedures appeared to enable patients to be treated fairly (Guidance Note 29).

Complaints
There is a complaints procedure in place and a log of complaints will be maintained (CoP Guidance Note 28).

Provision of costed treatment plans
The process for issuing patients with individualised costed treatment plans was explained to the inspection team and appeared compliant with CoP Guidance Note 4.3.

What the centre could do better.

Nothing noted.

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about storage (including cooling off periods) (Guidance Note 17)
- Information about intracytoplasmic sperm injection (Guidance Note 21)
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

Patient information was provided prior to the inspection and was considered by the inspection team to be comprehensive. The patient information was audited against SLC T58, T63 and the relevant guidance notes and was found to be compliant. The centre's website was compliant with the requirements of Chair's letter CH(11)02.

There is an SOP for providing information to patients (SLC T33b).

What the centre could do better.

Nothing noted.

Consent

- Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)
- Consent to legal parenthood (Guidance Note 6)

What the centre does well.

Written consent will be obtained before gametes or embryos are used in treatment or placed in storage (SLC T57) and this consent will be held in the patient records (SLC T46f). There is an SOP for obtaining this consent (SLC T33b).

Consent to legal parenthood will be obtained and centre staff understand the requirements in relation to legal parenthood. There are mechanisms in place to ensure that where a patient or second parent withdraws consent, the second parent or patient will be informed and in the case of the patient this will be before treatment takes place (SLC T64 and T65).

What the centre could do better.

Nothing noted.

3. Protection of gametes and embryos

Focus

The purpose of the inspection was to assess whether the centre has respect for the special status of the embryo when conducting licensed activities

Legal Requirements [Human Fertilisation and Embryology Act 1990 (as amended)]

- Licensed activities only take place on licensed premises
- Only permitted embryos are used in the provision of treatment services
- Embryos are not selected for use in treatment for social reasons
- Embryos are not created by embryo splitting
- Embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman
- Embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies
- Embryos which are or have been stored are not given to a person, other than in the course of providing treatment services, unless that person is a person to whom a licence applies
- No money or other benefit is given or received in respect of the supply of gametes or embryos unless authorised by the Authority

What the centre does well.

The centre will be conducting the activities essential to the provision of licensed activities at the licensed premises only (SLC T1).

Only permitted embryos will be used in the provision of treatment services. Embryos will not be selected for use in treatment for social reasons and will not be created by embryo splitting. Centre staff are aware that embryos must only be created where there is a specific reason to do so and the clinician responsible for the patient will document the justification of the use of gametes and embryos based on the patient's medical history and therapeutic indications (SLC T49). Embryos will only be stored for treatment services.

Staff are aware of the requirements of General Directions 0001, in respect of compensation for gamete and embryo donors.

What the centre could do better.

Nothing noted.

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17)

What the centre does well.

Before gametes or embryos are stored patients will be screened in accordance with SLC T50 or T52 as appropriate.

The centre staff explained how the bring forward system would work to ensure that gametes and embryos are not stored beyond their consented storage period (SLC T79, T80 and T81). The system appeared to be robust.

There is the facility to provide information about counselling and mediation services in cases where disputes arise when one gametes provider withdraws consent to the storage or use in treatment of gametes and embryos.

There is a process in place to deal with the cooling off period and staff demonstrated their understanding of this (CoP guidance note 5.35).

What the centre could do better.

Nothing noted.

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15)
- Export of gametes and embryos (Guidance Note 16)
- Receipt of gametes and embryos (Guidance Note 15)
- Import of gametes and embryos (Guidance Note 16)

What the centre does well.

Centre staff demonstrated their understanding of the requirements for distribution, receipt, import and export of gametes and embryos (SLC T105, T106, T107, T108, T109 and T110).

A courier will be used for transport of gametes or embryos and there is a third party agreement in place (SLC T111).

What the centre could do better.

Nothing noted.

Use of embryos for training staff (Guidance Note 22)
What the centre does well. There is the option for patients to consent to the use of their gametes or embryos in training (SLC T94). Embryos will only be used for the purposes of training staff in embryo biopsy, embryo storage or other embryological techniques and activities that are expressly authorised by the Authority (SLC T93).
What the centre could do better. Nothing noted.

4. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the centre:

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and embryos within the UK, including
    - maintaining up-to-date awareness and understanding of legal obligations
    - responding promptly to requests for information and documents from the HFEA
    - co-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare

Record keeping

- Record keeping and document control (Guidance Note 31)

What the centre does well.

Documents were seen to be controlled, with version numbers and review dates (SLC T34).

The content of patient records as required by SLC T46 was discussed with staff. Staff confirmed that the required elements will be included.

Procedures are in place to ensure that records are protected from unauthorised access and amendment (SLC T47). These measures include secure notes storage and password protection on the computers.

Records will be held for a minimum of 30 years and there is the facility to hold records for longer where circumstances require (SLC T48, T103 and T104).

What the centre could do better.

Nothing noted.

Legal requirements [Human Fertilisation and Embryology Authority 1990 (as amended)]

- Obligations and reporting requirements of centres (Guidance Note 32)

What the centre does well.

There is an SOP for submitting data to the HFEA (SLC T33b). Staff confirmed that they are familiar with submitting data to the HFEA and the PR is satisfied with the competence of staff in this area (SLC T15a).

Staff are aware of the requirements of General Directions 0005.

What the centre could do better.

Nothing noted.

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)
- Disclosure of information, held on the HFEA Register, for use in research

What the centre does well.

The inspection team considered that there is good provision for maintaining the confidentiality and privacy of patients. Patients will be identified by reference to their photographic identification and a copy of their photographic identification will be retained in the patient's notes.

Computers are password protected and paper records can be stored securely on the premises. Access to critical areas is restricted by key pad locks for key operated locks.

Staff are aware of the option for patients to consent to disclose their information for use in research.

What the centre could do better.

Nothing noted.

Areas of proposed practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of potential non compliance. Each area is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. At the time of the inspection not all the necessary equipment was present at the centre (SLC T17).	The PR should ensure that all required equipment is in place and validated prior to treatment being offered. The inspector should be informed when all the equipment is in place.	The remaining equipment required for treatment to be performed is on order and will be subject to validation prior to commencing treatment. Validation records of the laboratory equipment has been provided. Validation records of vital statistics monitoring equipment, ventilator and follicle aspiration pump will be provided to the HFEA in due course.	The Executive considers this to be a suitable response and will await confirmation from the PR that the equipment is in place and has been validated. On completion of validation of critical equipment the PR should submit a list of all critical equipment including the date of validation. A sample of validation documentation will be requested for review. Further action required.

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. The air quality in the processing areas has not been assessed (SLC T20).	The PR should ensure the air quality in the processing areas is assessed and meets the requirements of SLC T20 before treatment is offered. The results of the assessment should be forwarded to the inspector before the first treatment occurs.	The results of the air quality and VOC testing of the processing areas and background air quality have been provided to the inspectors since the inspection. All results meet the requirements of SLC T20.	The Executive has received and reviewed the results of the air quality testing. The results meet the requirements of SLC T20. No further action required.
3. The lead embryologist is not yet registered with the HCPC (SLC T14).	The PR should inform the inspector when the lead embryologist receives confirmation that her HCPC registration application has been accepted. By 16 January 2013.	The Person Responsible will provide this confirmation as soon as it is received.	The Executive considers this to be a suitable response and will confirm the embryologist's registration when informed that it has been accepted. Further action required.

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
4. Centre staff proposed that counselling would take place in one of the consultation rooms. The PR should consider whether a more suitable environment could be found at the centre (CoP Guidance Note 3.11).	The PR should inform the inspector whether a more suitable room has been found, or how she considers the consultation room to be suitable for counselling. Immediately.	A counselling room has been identified on the fourth floor and will be furnished and equipped to create a more suitable environment for counselling as soon as possible. The inspector will be kept informed of progress and evidence will be provided (photographs) and the inspector will be invited to return to the Centre.	The Executive considers this to be a suitable response and will await confirmation from the PR as to when the new counselling room is ready for use. Further action required.

Additional information from the Person Responsible
The team at the Centre would like to thank the HFEA inspectors for adopting a constructive approach at the time of inspection. The team found the inspection most helpful.

HFEA Licence Committee Meeting

29 November 2012

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 1

Centre 0324 (City Fertility) – Initial Inspection Report

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair Rebekah Dundas (lay) (videoconference) Sue Price (professional) Jane Dibblin (lay)	Lauren Crawford Legal Adviser: Sarah Ellson, Field Fisher Waterhouse

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee

- Cover sheet
- Initial inspection report
- Application form
- Confirmation from PR
- CV of proposed PR
- References (x2) for proposed PR
- CV of proposed LH

The Committee also had before it

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation

- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. The Committee noted that an initial enquiry was received by the HFEA from City Fertility in February 2012, regarding licensing requirements for a treatment and storage centre.

2. The Committee noted that City Fertility has been incorporated as a private limited company located at:

   16 St John Street
   London
   EC1M 4NT

3. The Committee noted that the application is for a licence for treatment and storage at a new centre.

4. The Committee noted that at the time of the inspection, the Inspectorate reported that there were a number of areas on practice that required improvement, including one area of critical non-compliance, two areas of major non-compliance and one 'other' area of non-compliance or poor practice.

5. The Committee noted that since the inspection the Person Responsible (PR) has provided evidence to the Inspectorate that one major area of non-compliance has been fully implemented.

6. The Committee noted that the Person Responsible has given a commitment to fully implement the following recommendations:

Critical area of non-compliance:

- **The PR should ensure that all required equipment is in place and validated prior to treatment being offered.**

Major areas of non-compliance:

- The PR should inform the inspector when the lead embryologist receives confirmation that her Health and Care Professions Council (HCPC) registration application has been accepted.

'Other' areas of practice that require improvement:

Initially the PR was required to inform the inspector whether a more suitable counselling room could be found, or how she considered the consultation room to be suitable for counselling. A counselling room has

been indentified on another floor and the Executive await confirmation from the PR as to when the new counselling room is ready for use.

7. The Committee noted the Inspectorate's recommendation to grant the centre's licence for a two year period without additional conditions, subject to the proposed PR providing evidence of compliance with the non-compliance detailed in the report and to also appoint the proposed PR and Licence Holder (LH).

Discussion

8. The Committee referred to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and noted that the executive had received the supporting information required by General Direction 0008.

9. The Committee was satisfied that the character of the proposed PR, Jane Holman, is such as required for the supervision of the licensed activities and that the PR will discharge the duties under section 17 of the HF&E Act 1990 (as amended).

10. The Committee noted that the proposed PR holds academic qualifications in the field of nursing and is registered with the Nursing and Midwifery Council (NMC); registration number: 89J1425E. The proposed PR also has more than two years' practical experience which is directly relevant to the activity to be authorised by the licence as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii). She has successfully completed the HFEA PR Entry Programme and has two satisfactory references.

11. The Committee considered that the proposed PR is suitable.

12. The Committee was also satisfied regarding the suitability of the proposed Licence Holder, Andrew Berkley, having seen his CV. The Committee noted that the licence application concerns treatment and storage services which relate to gametes or embryos intended for human application.

13. The Committee was satisfied that premises to be licensed are suitable for the conduct of licensed activities based on evidence provided within the report. The Committee noted that, at inspection, the premises appeared appropriate for the proposed licensable activities and the Inspectorate considered that the premises should provide a safe, clean and private environment for patients, their gametes and embryos and centre staff. The premises have been handed over by the contractors to the centre and building regulation certification was made available on the day of the inspection.

14. The Committee noted that the application includes the use of embryos for training, and was satisfied that this activity was necessary and desirable for that purpose.

15. The Committee referred to 'Guidance on periods for which new or renewed licences can be granted'. The Panel took into account matters set out in paragraph 4.2 and noted that it states that "[The Licence Committee] will normally grant an initial treatment/storage licence for up to two years. This is because in granting an initial licence, there will be no history of compliance to support a longer licence."

16. The Committee noted the Inspectorate's recommendation for a two year licence, without additional conditions, subject to the proposed PR providing evidence of compliance with the non-compliance detailed in the report.

Decision

17. The Panel agreed to appoint Jane Holman as the Person Responsible for City Fertility (Centre 0324) with immediate effect, in accordance with section 18A of the HFE Act 1990 (as amended).

18. The Panel agreed to appoint Andrew Berkley as the Licence Holder for City Fertility (Centre 0324) with immediate effect.

19. The Committee agreed to grant the centre's licence for a period of two years with no additional conditions, subject to the proposed PR providing evidence of compliance with the outstanding recommendations detailed in the report and referenced in paragraph 6 of these minutes.

Signed: Date: 10/12/2012

DW Arch

David Archard (Chair)